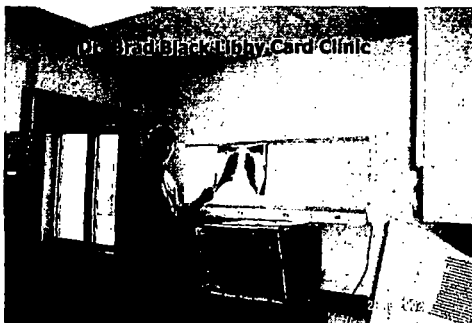


## Libby: Health Information

- **What is the nature & extent of health effects associated with Libby Amphibole exposures ?**

Aubrey Miller, MD, MPH

US EPA Region 8



## Asbestos Health Effects

- **Non-Cancer Fibrosis/Scarring** (latency >10 yrs)
  - Asbestosis – scarring of the air sacs
  - Pleural Fibrosis – scarring of lining around the lung
  - Pleural Effusions
- **Cancer** (latency 20-40 yrs)
  - Lung Cancer
    - Increased risk of all lung cancer types, especially with smoking
  - Mesothelioma
    - Rapidly fatal cancer of the lining around the lungs & abdomen
    - Virtually all cases associated with asbestos exposure
    - Not affected by smoking
  - Other Cancers
    - Gastrointestinal & laryngeal

## Historical Libby-related Health Data

### ■ Libby Site

#### ■ Amandus (NIOSH; 1987) & McDonald Studies (1986)

- Mortality: Increased risk asbestosis & lung cancer
- Morbidity: Increased interstitial & pleural disease (x-rays)
- McDonald Update (2004): risk of mesothelioma in Libby miners 10x that of chrysotile miners in Quebec; similar to crocidolite miners.

### ■ Other Sites Processing Libby Vermiculite

- Lockey et al, 1984: – OM Scott, Ohio: CXR abnormalities in 5% (n=513) of workers, pleural effusions, symptoms;
  - Lockey Follow-up (2005): 26% Pleural abnormalities in same cohort

## Libby Worker Mortality Studies

JC McDonald (McGill University)\*

Studies	< July 1983	Total
Lung CA SMR	2.45	2.40
NMRD** SMR	2.55	3.09
Mesothelioma Cases	8	12

• 406 workers Hired prior to 1963 and followed till 1999

• Worked at least 1 year

\*\* Non-malignant respiratory disease (includes asbestosis)

McDonald JC, Harris J, Armstrong B. Mortality in a cohort of vermiculite miners exposed to fibrous Amphibole in Libby, Montana. Occup Environ. Med. 2004; 61:363-366.

## Libby Worker Mortality Studies JC McDonald (McGill University)

**Table 3** Poisson regression estimates of relative risk of death from lung cancer, non-malignant respiratory disease (NMRD), and all causes in relation to cumulative exposure

Certified cause of death	Cumulative exposure	Deaths observed (expected)	Adjusted relative risk (95% CI)	p value
Respiratory cancer	1: 0- (8.6)	5 (4.3)	1.00	0.02
	2: 11.7- (16.7)	9 (4.1)	1.74 (0.58 to 5.23)	
	3: 25.2- (53.2)	10 (4.1)	1.85 (0.63 to 5.45)	
	4: 113.8- (393.8)	16 (4.6)	3.20 (1.16 to 8.84)	
	Linear model (per 100 f/ml.y)		0.36 (0.03 to 1.20)	
NMRD	1: 0- (8.6)	5 (3.5)	1.00	0.0001
	2: 11.7- (16.7)	13 (3.7)	2.53 (0.88 to 7.24)	
	3: 25.2- (53.2)	14 (3.8)	2.62 (0.93 to 7.27)	
	4: 113.8- (393.8)	19 (4.1)	3.11 (1.15 to 8.44)	
	Linear model (per 100 f/ml.y)		0.38 (0.12 to 0.96)	
All deaths	1: 0- (98.6)	55 (45.6)	1.00	0.0003
	2: 11.7- (16.7)	59 (47.1)	0.97 (0.66 to 1.41)	
	3: 25.2- (53.2)	66 (48.0)	1.08 (0.75 to 1.56)	
	4: 113.8- (393.8)	90 (53.7)	1.42 (1.01 to 2.01)	
	Linear model (per 100 f/ml.y)		0.14 (0.05 to 0.26)	

All analyses exclude deaths and person-years in the first 10 years of follow up.

## Libby Worker Mortality Studies NIOSH 2007\*

Standardized Mortality Rates (SMRs)	
All Causes	1.2
Respiratory	1.7
Asbestosis	165.8
Mesothelioma (Total n=15; SMR based on 1999-2001 n=2)	15.1

- **1,672 workers hired from 1935 – 1981.**
- **Follow-up through December 2001.**

Sullivan, P. Vermiculite, Respiratory Disease and Asbestos Exposure in Libby, Montana: Update of a Cohort Mortality Study. *Env. Health Perspectives* (On line Jan. 3, 2007. doi:1289/ehp.9481 at <http://dx.doi.org/>)

## Libby Worker Mortality Studies NIOSH 2007

- Non-Malignant Respiratory Disease excess mortality:
  - Those < 4.5 f/cc-years exposure
  - Even among those who worked < 1 year
    - SMR 1.9 for those <3.5 f/cc-years
    - SMR 2.6 for those >15 f/cc-years
- Lung Cancer excess mortality:
  - Years of Work
    - < 1 year: SMR 1.6
    - > 10 years: SMR 2.5

## Historical Libby-related Health Data Non-Occupational

• Libby Case Reports per local MDs

• Other Sites

-Srebro & Roggli, 1994\* (Tissue Data)

MN Child exp: asbestosis & lung Cancer age 42



\* Srebro SH, Roggli VL. Asbestos-related disease associated with exposure to asbestiform tremolite. Am J Ind Med. 1994 Dec;26(6):809-19.

## Libby Community Studies Since 1999

- **Mortality Studies (NIOSH & ATSDR)**
- **Libby medical testing over 7300 participants (\$11 million) (Group)**
- **CT scan study of individuals with indeterminate CXR's (ATSDR)**
- **Progression of disease Study (Dr. Alan Whitehouse)**
- **Case-Series to identify non-occupational disease (ATSDR)**



## Community Based Mortality Studies

- **NIOSH:**\*
  - Lincoln County, Montana: asbestosis rate ~ 40X US rate;
  - Age-adjusted rate 1988-1997 was highest in the US
- **ATSDR:** (20 year study period: 1979 – 1998)
  - Increased risk compared to MT & US populations
    - Asbestosis: 40-80x higher
    - Lung Cancer: 20-30% higher
    - Mesothelioma: marked increase (rate not quantifiable)
      - Observed 3/~ 2500 (deaths outside county not counted)
      - Expected: typically estimated <10/million

\* Evaluation NCHS data per R. Castellon, MD; NIOSH/DRDS

## **Medical Screening\***

Summer 2000 & 2001 > 7300 Tested

- **Eligible**
  - Lived/worked in Libby at least 6 months prior to 1990; 18 y/o
- **Testing**
  - Medical & Exposure History
  - Chest x-rays (3 views: PA, right & left obliques)
  - Pulmonary Function Testing (FVC, FEV1, FEV1/FVC ratio)
- **Interpretations (reviewers blinded to history)**
  - + CXR = at least 2/3 expert B-readers recorded abnormalities

\* Funded by EPA, led by ATSDR & PHS

## **Prevalence of pleural abnormalities**

Asbestos-related x-ray changes

- **Libby Site: 18 %**
  - 5 % with no apparent exposure - 24% with 6+ pathways
  - No control group but internal dose-response associations clear
  - >75% of those with abnormalities are non-workers, non-family members
- **Other US Studies:**
  - 0.2%: 1422 blue-collar workers in North Carolina (Castellan 1985)
  - 0.9%: 693 loggers in Washington and Oregon (Stibolt 1991)
  - 1.8%: 326 New Jersey residents (Anderson 1979)
  - 2.3%: 1212 patients at VA hospitals in NJ (Miller JA 1996)
  - 3.9%: cross-sectional 1060 US adults, workers included (Rogan 2002)



## Crude Pleural Abnormality Rates (%) All CXR Views, 2/3 B-readers

<b>All Participants</b>		<b>18 % *</b>	
			<u>Play Verm. Piles</u>
Ever WRG employed	48.5	Sometimes	18.7
Secondary Contractor	36.8	Frequently	26.0
Lived with WRG worker	25.5	<u>Popped Verm.</u>	
		Sometimes	21.7
		Frequently	25.4
		<u>Vermiculite Gardening</u>	20.3
<u>Hand. Verm. Insulation</u>		<u>Recreated along road to mine</u>	
Sometimes	20.9	Sometimes	17.4
Frequently	26.6	Frequently	21.7
<u>Verm. Insul. In Home</u>	19.8	<u>Played Ball/Expan. Plant</u>	
		Sometimes	14.8
		Frequently	18.8

\* PA view only 14%. n= 7307 participants

## ATSDR High-Resolution CT Study\* Indeterminate Chest X-rays

- 353 participants in the medical screening that had 1 of 3 B-reads as positive for pleural abnormalities.
- Three Expert Readers (Positive = 2/3 readers)

Group	% Positive
Total (353)	28%
Workers (55)	40%
Household Contacts (99)	48%
Non-Occupational/Recreational (199)	15%

\* Muravov, OI et. al. The usefulness of computer tomography in detecting asbestos-related pleural abnormalities in people who had indeterminate chest radiographs: the Libby, Montana, experience. Int. J. Hyg. Env. Hlth. 2005; 208; 87-99.

## Asbestos Pleural Disease Implications\*

- **Increased Risk of Malignancy**
  - lung cancer & mesothelioma
- **Functional Impairment & Increased Symptoms**
  - Both circumscribed & diffuse disease
- **Progression** (radiologically & physiologically)
  - Treating physician of Libby patients
    - 94/123 (76%) patients followed over time had significant decline in pulmonary function (Whitehouse, 2004)
  - Case-reports:
    - 65 year-old dies of progressive asbestosis; only reported exposures 2 summers at ages 18 & 19 in California vermiculite processing facility (Wright, 2002); Also see (Srebro & Rogli, 1994)
  - Other studies
    - 37% of amosite workers with < 1 month exposure had progression of interstitial & pleural disease 20 years after end of exposure (Erich 1992)

Clinical Review Summer 2006: Directors NIEHS, ATSDR, Univ. Cincinnati, Mt. Sinai Hospital

\* ATS 2004. Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos. Official Statement of the American Thoracic Society Adopted December 12, 2003. Am J Resp Crit Care Med 2004;170:691-715.

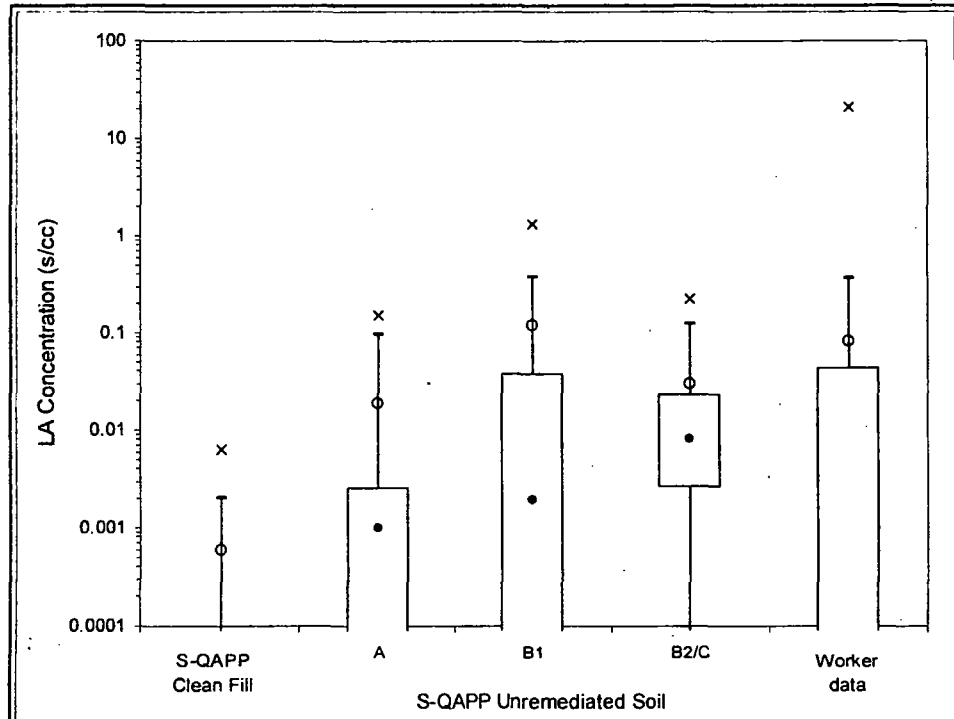


## Critical Exposure Data Issues

- Solid Matrix Sampling Insufficient for Clean Up Decisions
- The Completed Exposure Pathways in the CSM are not Properly Quantified
- Current Clean Up Efficacy has not Been Evaluated
- Nature and Extent Data are not Complete for the Mine and Troy (Traditional RI)

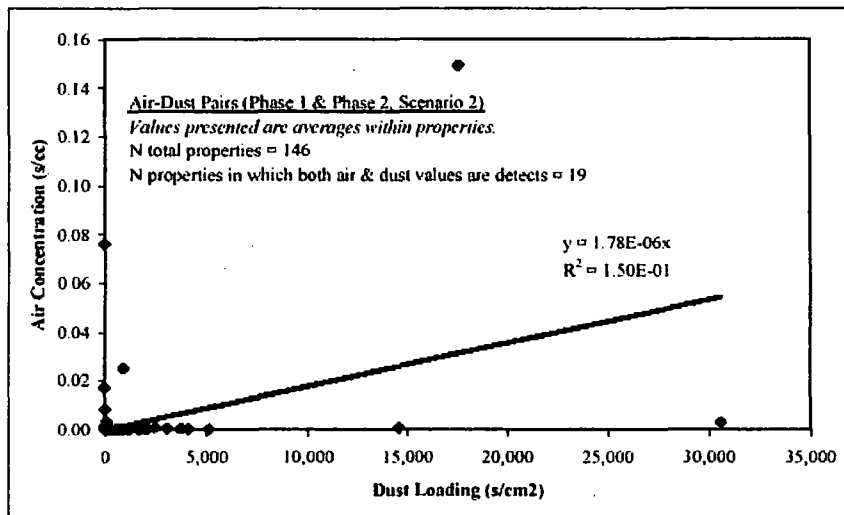
## Solid Matrix Sampling

- Soils That are Non-Detect by PLM Still Generate Significant Airborne Fibers When Disturbed
- The Relationship Between LA Contamination of Indoor Dust to Indoor Air is Poorly Understood



Metric	S-QAPP Clean Fill	S-QAPP Unremediated Soil			Worker data (OU4)
		A	B1	B2/C	
N	21	10	21	13	1434
DF	24%	60%	67%	77%	43%
Max	0.006	0.150	1.34	0.23	21.0
95%	0.002	0.097	0.374	0.123	0.359
75%	0.000	0.003	0.037	0.023	0.043
50%	0.000	0.001	0.002	0.008	0.000
25%	0.000	0.000	0.000	0.003	0.000
5%	0.000	0.000	0.000	0.000	0.000
BE	0.00059	0.019	0.12	0.029	0.082
UCL	7.75E-03	2.85E+05	5.13E+03	6.88E-01	1.61E-01
UB	0.0064	0.15	1.3	0.23	0.39

## Indoor Dust to Indoor Air



## Combined CSM/Efficacy Sampling

- The "Big Three" Pathways
  - Outdoor Ambient Air
  - Indoor Air (ABS)
  - Outdoor Air Around LA Contaminated Soils (ABS)
- Transportation Corridors
- The Rest

## Nature and Extent

- Mine
  - Extent of Soil Contamination
  - Stream Transport
  - Airborne Transport
  - Surrounding Trees
- Troy
  - How Many Properties Impacted?